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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/729,460      | 12/05/2000  | Karl Kolter          | 51007               | 4443             |

7590 03/26/2002

Messrs. Keil & Weinkauff  
1101 Connecticut Ave., N.W.  
Washington, DC 20036

EXAMINER

DEWITTY, ROBERT M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/729,460

Applicant(s)

KOLTER ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 March 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) 11-13 is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-14 are pending in the instant application. Claims 1-6 and 14 are withdrawn from further consideration.

#### ***Election/Restrictions***

1. Applicant's election with traverse of Group II in response to the Office Action mailed 1/10/02 is acknowledged. The traversal is on the ground(s) that the inventions possess commonality. This not found persuasive because as shown in the mentioned Office Action, the inventions are distinct as shown by their different classification, and recognized divergent subject matter.

The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cherukuri et al. (U.S. Pat. No. 4,931,293)

Cherukuri relates to a delivery system for food acids that can be made using a

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coating formed from emulsifier and polyvinyl acetate. The system concerns chewing gum compositions having prolonged acid release during mastication (col. 5, lines 21-40). The delivery system is comprised of: polyvinyl acetate (from 30-93% by weight), emulsifiers (from about 4% to 30% (col. 8, lines 56-58)), and acid such as citric acid, malic acid, ascorbic acid, fumaric acid, tartaric acid, or succinic acid (col. 5, lines 26-29). It is taught the coatings possess sufficient hydrophilic character to swell to some degree in the presence of water, thereby slowly releasing the core material (col. 5, lines 50-52). The coating is useful for a variety of core materials, including pharmaceutical preparations (col. 6, line 16) drug and other particulate materials, and for taste-masking (Id. at line 29).

4. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (U.S. Pat. No. 4,931,293), further in view of Khankari et al. (U.S. Pat. No. 6,221,392).

As discussed above, Cherukuri teaches a delivery system comprised of polyvinyl acetate, emulsifiers, and acids, such system that performs taste-masking. However, Cherukuri does not teach using a disintegrant in the formulation.

Khankari relates to a direct oral dosage form that dissolves rapidly. Along with active ingredients (col. 4, lines 50-60), the dosage can include wicking agents. It is taught that the wicking agents are used to help transport moisture into the interior of the dosage form, thereby allowing them to dissolve from the inside as well as the outside (col. 13, line 60-64). Suitable wicking agents include croscarmellose and crosslinked polyvinylpyrrolidone (col. 14, lines 1-5).

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Motivation to utilize a wicking agent in conjunction with the delivery system of Cherukuri would have arisen because Cherukuri requires that the coatings swell to some degree to thereby allow slow releasing of the core material. As Khankari teaches wicking agents that are suitable for transporting moisture into the interior of the dosage form, one with ordinary skill would have incorporated such wicking agent into the delivery system of Cherukuri.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD  
March 25, 2002

  
**ALLEN J. ROBINSON**  
**PRIMARY EXAMINER**